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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,599	09/26/2003	Kenneth Reever	BSC-157DV	1962

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EXAMINER

BOGART, MICHAEL G

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,599

Applicant(s)

REEVER, KENNETH

Examiner

Michael G. Bogart

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-23 and 29-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20, 21 and 29-34 is/are allowed.
- 6) ☒ Claim(s) 18, 19 and 23 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>26 Sept. 2003</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement (IDS)

The IDS has been considered except for "ICN Patient Handbook" by Manhattan *et al.* This document is not available in the present file. The URL listed with the PTO form 1449 does not lead to that document. A 2 page web document with the same title, author and date was located and considered, see enclosed PTO form 892.

Claim Rejections - 35 USC § 103

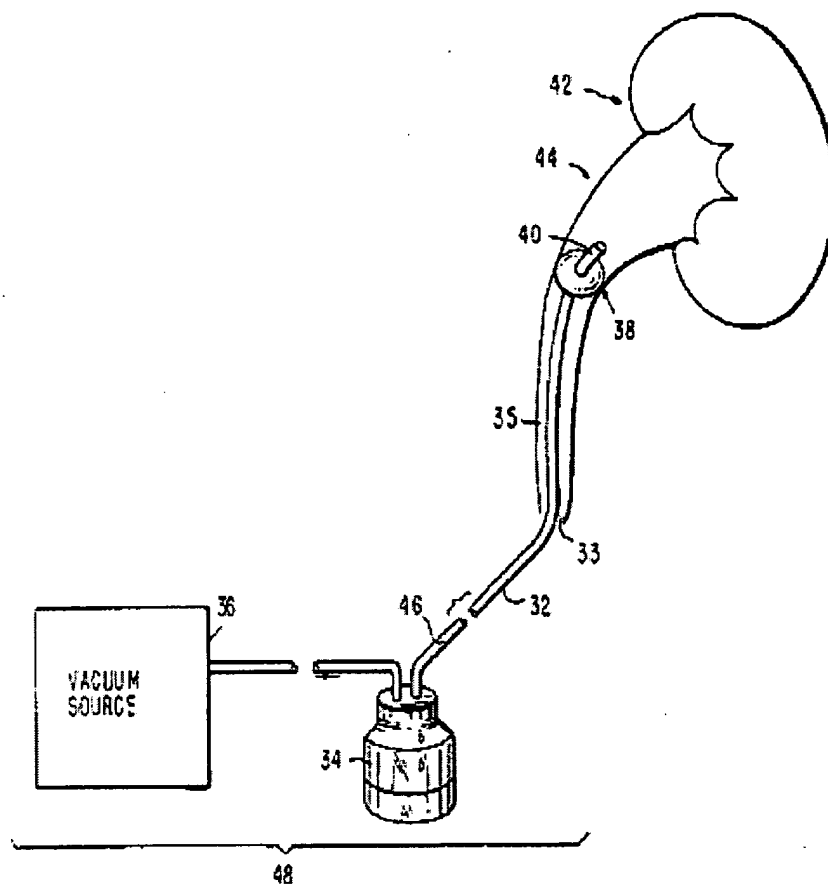
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ikeguchi (US 6,500,158 B1).

Ikeguchi teaches a first catheter (32) positionable in a patient's first ureter (35), the first catheter (32) having a proximal and a distal end (40, 46), the proximal end (40) of the catheter (32) including a ureter to catheter seal (38), the distal end (46) of the catheter capable of passing through the patient's urinary sphincter, the distal end (46) of the catheter capable of being connected to an external urine collector (34)(see fig. 2, below).

Ikeguchi expressly discloses the claimed invention except for there being two catheters, one for each ureter of a patient.



Generally, mere duplication of parts is not sufficient to patentably distinguish an invention from the prior art unless a new and unexpected result is produced. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). MPEP § 2144.04.

In the present case, it would have been obvious to one of ordinary skill in the art to modify the system of Ikeguchi to include two catheters in order to provide for patients who need simultaneous treatment of both ureters.

Claim 19 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ikeguchi as applied to claim 18 above, and further in view of Willingham (US 5,411,495 A).

Ikeguchi does not disclose a valve.

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Willingham teaches a conventional urine catheter including a valve (62) between the distal end of the catheter (16) and the patient's urethra (fig. 1). The one way valve prevents backflow of urine to the urethra. At the time of the invention, it would have been obvious to one of ordinary skill in the art to add a valve to the distal end of the catheter of Ikeguchi in order to prevent backflow.

Claim 23 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ikeguchi as applied to claim 18 above, and further in view of Bosley (US 5,289,831 A).

Ikeguchi does not disclose the specific type of material from which the catheters are constructed.

Bosley teaches catheters, stents and the like which are constructed from polyethylene, polypropylene and other suitable materials which are medical grade and can readily be made sterile (col. 12-line 47-col. 13, line 40).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to select one of the exemplary materials of Bosley to construct the catheters of Ikeguchi in order to provide proven, readily available medical grade construction.

Allowable Subject Matter

Claims 20, 21 and 29-34 are allowed.

Claim 22 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claims 20, 21, 30 and 32-34, no art of record teaches 1st and 2nd catheters extending from the 1st and 2nd ureters of a patient, the catheters including ureter seals, the ends of the catheters both attached to a third catheter which is in turn connected to an external collection container.

Regarding claims 29 and 31, the closest art of record, Ikeguchi, teaches catheter systems that extend through the urinary system, while the instant invention uses direct surgical incisions to access the ureters.

Regarding claim 22, Ikeguchi does not teach any kind of adhesive used in conjunction with inflatable seal (38).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the examiner's supervisor, Larry Schwartz may be reached at phone number (571) 272-4390. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 272-3700.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 306-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Bogart
2 December 2004



Larry I. Schwartz
Supervisory Patent Examiner
Group 3700